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Section 5 – 510 (k) Summary

MAY 18 2007

(As required by 21 CFR 807.92(c) and 21 CFR 807.93)

NAME OF SPONSOR:	DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, Indiana 46582 Establishment Registration Number: 1818910
510(K) CONTACT:	Natalie Heck Manager, Regulatory Affairs Telephone: (574) 372-7469 Facsimile: (574) 371-4987 Electronic Mail: NHeck@dpyus.jnj.com
510(K) PREPARER:	Rebecca Lennard Independent Contractor Electronic Mail: RLennard@dpyus.jnj.com
DATE PREPARED:	October 16, 2006
PROPRIETARY NAME:	DePuy Pinnacle® Constrained Acetabular Liner
COMMON NAME:	Acetabular Cup Liner
CLASSIFICATION:	Class II per 21 CFR 888.3310, Hip joint metal/polymer/metal, constrained, cemented or uncemented prosthesis
DEVICE PRODUCT CODE:	87 KWZ
SUBSTANTIALLY EQUIVALENT DEVICE:	DePuy Pinnacle® Constrained Acetabular Liner, K052079 DePuy Pinnacle® Constrained Acetabular Liner, K043058 DePuy Modular M Femoral Head, K060031

DEVICE DESCRIPTION:

The DePuy Pinnacle® Constrained Acetabular Liner is part of a modular system designed to replace the natural articular surface of the hip joint in total hip replacement. The liner is manufactured from ultra high molecular weight polyethylene (UHMWPE), which locks into a porous coated, hemispherical outer shell component manufactured from titanium alloy (Ti-6A1-4V). The liner component articulates with a metal femoral head of an appropriate diameter.

The Pinnacle® Constrained Acetabular Liner mechanically constrains the femoral head within the ID of the liner by providing greater than 180 degrees femoral head capture combined with a titanium constraining ring which fits over the opening diameter of the liner. The UHMWPE liner is held in the metal shell by means of a titanium locking ring.

The subject DePuy Pinnacle® Constrained Acetabular Liners are UHMWPE acetabular cup liners that are available in a lateralized neutral or lateralized face-changing orientation and have inner diameters (ID) compatible with Self-Centering™ (bipolar) femoral heads within the 40mm – 44mm size range. The liners are identical in design to those cleared in K052079 on October 21, 2005. The compatible components are being extended in this submission to include DePuy Modular M femoral heads (cleared in K060031 on January 31, 2006) within the 40mm – 44mm size range.

INTENDED USE AND INDICATIONS:

Intended Use:

The subject Constrained Liner is intended to be used with the DePuy Pinnacle® metal acetabular shells, DePuy Modular M femoral heads and Self-centering™ (bipolar) femoral heads to resurface the acetabular socket in cementless total hip arthroplasty.

Indications for Use:

The Pinnacle® Constrained Acetabular Liner is indicated for use as a component of a total hip prosthesis in primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease or intraoperative instability.

The Pinnacle® Constrained Acetabular Liner is indicated for use with the Pinnacle® Acetabular Cup in cementless application.

BASIS OF SUBSTANTIAL EQUIVALENCE:

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The DePuy Pinnacle® Constrained Acetabular Liner described in this submission is identical to the DePuy Pinnacle® Constrained Acetabular Liner previously cleared in K052079 on October 21, 2005. There have been no design modifications to the Pinnacle Constrained Acetabular Liner. The DePuy Modular M femoral head compatible component described in this submission is identical to the DePuy Modular M femoral head previously cleared in K060031 on January 31, 2006. There have been no design modifications to the DePuy Modular M femoral heads.

The articulation of the DePuy Pinnacle Constrained Acetabular Liner with the DePuy Modular M femoral heads is substantially equivalent to the predicate device (K043058 cleared on March 14, 2005) based on similarities in design, intended use, material and manufacturing methods. The DePuy Modular M femoral head mating components, while not identical in size to the predicate, do not raise any new issues of safety or effectiveness.

DePuy believes that the articulation of the DePuy Pinnacle® Constrained Acetabular Liner and the DePuy Modular M femoral head is substantially equivalent to the previously cleared devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 18 2007

DePuy Orthopaedics, Inc.
% Ms. Natalie Heck
Manager, Regulatory Affairs
700 Orthopaedic Drive
Warsaw, Indiana 46582

Re: K071117
Trade/Device Name: DePuy Pinnacle® Constrained Acetabular Liner
Regulation Number: 21 CFR 888.3310
Regulation Name: Hip joint metal/polymer constrained cemented or uncemented prosthesis
Regulatory Class: Class II
Product Code: KWZ
Dated: April 19, 2007
Received: April 20, 2007

Dear Ms. Heck:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ- 410 DGRND
D.O.
f/t:ELF:afb:5/16/07

OC Numbers:

Division of Enforcement A	240-276-0115
Dental, ENT and Ophthalmic Devices Branch	240-276-0115
OB/GYN, Gastro. & Urology Devices Branch	240-276-0115
General Hospital Devices Branch	240-276-0115
General Surgery Devices Branch	240-276-0115
Division of Enforcement B	240-276-0120
Cardiovascular & Neurological Devices Branch	240-276-0120
Orthopedic, Physical Medicine & Anesthesiology Devices and Radiological Devices	240-276-0120

Section 4 – Indications for Use Statement

510 (k) Number (if known): K071117

Device Name: DePuy Pinnacle® Constrained Acetabular Liner

Indications for Use:

The Pinnacle® Constrained Acetabular Liner is indicated for use as a component of a total hip prosthesis in primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease or intraoperative instability.

The Pinnacle® Constrained Acetabular Liner is indicated for use with the Pinnacle® Acetabular Cup in cementless application.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(Please do not write below this line. Continue on another page if needed.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071117